

WHAT IS CLAIMED IS:

1. A method for maintaining calibration of a substantially continuous analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including two or more reference data points;

providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least two matching data pairs;

creating a conversion function based on said calibration set;

converting sensor data into calibrated data using said conversion function;

subsequently obtaining one or more additional reference data points and creating one or more new matched data pairs;

evaluating said calibration set when said new matched data pair is created, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pairs in said calibration set span a predetermined time range, 2) ensuring matched data pairs in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pairs over said predetermined time range, and 4) allowing matched data pairs only within a predetermined range of analyte values; and

subsequently modifying said calibration set if such modification is required by said evaluation.

2. The method of claim 1, wherein the step of evaluating said calibration set further comprises at least one of evaluating a rate of change of the analyte concentration, evaluating a congruence of respective sensor and reference data in said matched data pairs, and evaluating physiological changes.

3. The method of claim 1, wherein the step of evaluating said calibration set includes evaluating only said new matched data pair.

4. The method of claim 1, wherein the step of evaluating said calibration set includes evaluating all of the matched data pairs in said calibration set and said new matched data pair.

5. The method of claim 1, wherein the step of evaluating said calibration set includes evaluating combinations of matched data pairs from the calibration set and said new matched data pair.

6. The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream from a long-term implantable analyte sensor.

7. The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream that has been algorithmically smoothed.

8. The method of claim 1, wherein the step of receiving sensor data stream comprises algorithmically smoothing said data stream.

9. The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a cabled connection.

10. The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.

11. The method of claim 1, wherein the step of receiving reference data from a reference analyte monitor comprises receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

12. The method of claim 1, wherein the reference analyte monitor comprises self-monitoring of blood analyte.

13. The method of claim 1, wherein the step of creating a conversion function comprises linear regression.

14. The method of claim 1, wherein the step of creating a conversion function comprises non-linear regression.

15. The method of claim 1, wherein the step of forming a calibration set comprises including in said calibration set between one and six matched data pairs.

16. The method of claim 1, wherein the step of forming a calibration set comprises including six matched data pairs.

17. The method of claim 1, wherein the step of forming a calibration set further comprises determining a value for  $n$ , where  $n$  is greater than one and represents the number of matched data pairs in the calibration set.

18. The method of claim 17, wherein the step of determining a value for  $n$  is determined as a function of the frequency of the received reference data points and signal strength over time.

19. The method of claim 1, further comprising determining a set of matching data pairs from said evaluation of said calibration set and re-forming a calibration set.

20. The method of claim 19, further comprising repeating the step of re-creating said conversion function using said re-formed calibration set.

21. The method of claim 20, further comprising converting sensor data into calibrated data using said re-created conversion function.

22. A system for maintaining calibration of a substantially continuous analyte sensor, the system comprising:

- means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

- means for receiving reference data from a reference analyte monitor, including two or more reference data points;

- means for providing two or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

- means for forming a calibration set including at least two matched data pair;

- means for creating a conversion function based on said calibration set;

- means for converting sensor data into calibrated data using said conversion function;

- subsequently obtaining one or more additional reference data points and creating one or more new matched data pairs;

- means for evaluating said calibration set when said new matched data pair is created, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pairs in said calibration set span a predetermined time range, 2) ensuring matched data pairs in said calibration set are no older than a predetermined

value, 3) ensuring said calibration set has substantially distributed high and low matched data pairs over said predetermined time range, and 4) allowing matched data pairs only within a predetermined range of analyte values; and

means for modifying said calibration set if such modification is required by said evaluation.

23. The system of claim 22, wherein said means for evaluating said calibration set further comprises at least one of means for evaluating a rate of change of the analyte concentration, means for evaluating a congruence of respective sensor and reference data in matched data pairs; and means for evaluating physiological changes.

24. The system of claim 22, wherein said means for evaluating said calibration set includes means for evaluating only said one or more new matched data pairs.

25. The system of claim 22, wherein said means for evaluating said calibration set includes means for evaluating all of the matched data pairs in said calibration set and said one or more new matched data pairs.

26. The system of claim 22, wherein said means for evaluating said calibration set includes means for evaluating combinations of matched data pairs from the calibration set and said one or more new matched data pair.

27. The system of claim 22, wherein said means for receiving sensor data comprises means for receiving sensor data from a long-term implantable analyte sensor.

28. The system of claim 22, wherein said means for receiving sensor data comprises means for receiving sensor data that has been algorithmically smoothed.

29. The system of claim 22, wherein said means for receiving sensor data comprises means for algorithmically smoothing said receiving sensor data.

30. The system of claim 22, wherein said means for receiving reference data comprises means for downloading reference data via a cabled connection.

31. The system of claim 22, wherein said means for receiving reference data comprises means for downloading reference data via a wireless connection.

32. The system of claim 22, wherein said means for receiving reference data from a reference analyte monitor comprises means for receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

33. The system of claim 22, wherein said means for receiving reference data comprises means for receiving from a self-monitoring of blood analyte.

34. The system of claim 22, wherein said means for creating a conversion function comprises means for performing linear regression.

35. The system of claim 22, wherein said means for creating a conversion function comprises means for performing non-linear regression.

36. The system of claim 22, wherein said means for forming a calibration set comprises including in said calibration set between one and six matched data pairs.

37. The system of claim 22, wherein said means for forming a calibration set comprises including in said calibration set six matched data pairs.

38. The system of claim 22, wherein the means for forming a calibration set further comprises determining a value for  $n$ , where  $n$  is greater than one and represents the number of matched data pairs in the calibration set.

39. The system of claim 38, wherein the means for determining a value for  $n$  is determined as a function of the frequency of the received reference data points and signal strength over time.

40. The system of claim 22, further comprising means for determining a set of matching data pairs from said evaluation of said calibration set and re-forming a calibration set.

41. The system of claim 40, further comprising said means for repeating the set of creating said conversion function using said re-formed calibration set.

42. The system of claim 41, further comprising means for converting sensor data into calibrated data using said re-created conversion function.

43. A computer system for maintaining calibration of a substantially continuous analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including two or more reference data points;

a data matching module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set including at least two matched data pairs;

a conversion function module that creates a conversion function using said calibration set;

a sensor data transformation module that converts sensor data into calibrated data using said conversion function; and

a calibration evaluation module that evaluates said calibration set when said new matched data pair is provided, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pairs in said calibration set span a predetermined time period, 2) ensuring matched data pairs in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pairs over a predetermined time range, and 4) allowing matched data pairs only within a predetermined range of analyte values,

wherein said conversion function module is programmed to re-create said conversion function of such modification is required by said calibration evaluation module.

44. The computer system of claim 43, wherein said evaluation calibration module further evaluates at least one of a rate of change of the analyte concentration, a congruence of respective sensor and reference data in matched data pairs; and physiological changes.

45. The computer system of claim 43, wherein said evaluation calibration module evaluates only said new matched data pair.

46. The computer system of claim 43, wherein said evaluation calibration module evaluates all of the matched data pairs in said calibration set and said new matched data pair.

47. The computer system of claim 43, wherein said evaluation calibration module evaluates combinations of matched data pairs from the calibration set and said new matched data pair.

48. The computer system of claim 43, wherein said sensor data receiving module receives said data stream from a long-term implantable analyte sensor.

49. The computer system of claim 43, wherein said sensor data receiving module receives an algorithmically smoothed data stream.

50. The computer system of claim 43, wherein said sensor data receiving module comprises programming to smooth said data stream.

51. The computer system of claim 43, wherein said reference data receiving module downloads reference data via a cabled connection.

52. The computer system of claim 43, wherein said reference data receiving module downloads reference data via a wireless connection.

53. The computer system of claim 43, wherein said reference data receiving module receives within a receiver internal communication from a reference analyte monitor integral with said receiver.

54. The computer system of claim 43, wherein said reference data receiving module receives reference data from a self-monitoring of blood analyte.

55. The computer system of claim 43, wherein said conversion function module comprises programming that performs linear regression.

56. The computer system of claim 43, wherein said conversion function module comprises programming that performs non-linear regression.

57. The computer system of claim 43, wherein said calibration set module includes in said calibration set between one and six matched data pairs.

58. The computer system of claim 43, wherein said calibration set module includes in said calibration set six matched data pairs.

59. The computer system of claim 43, wherein the calibration set module further comprises programming for determining a value for  $n$ , where  $n$  is greater than one and represents the number of matched data pairs in the calibration set.

60. The computer system of claim 59, wherein said programming for determining a value for  $n$  determines  $n$  as a function of the frequency of the received reference data points and signal strength over time.

61. The computer system of claim 43, wherein data matching module further comprises programming to re-form said calibration set based on said calibration evaluation.

62. The computer system of claim 61, wherein said conversion function module further comprises programming to re-create said conversion function based on said re-formed calibration set.

63. The computer system of claim 62, sensor data transformation module further comprising programming for converting sensor data into calibrated using said re-created conversion function.

64. A method for maintaining calibration of a glucose sensor, the method comprising:

- receiving a data stream from an analyte sensor, including one or more sensor data points;

- receiving reference data from a reference analyte monitor, including two or more reference data points;

- providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

- forming a calibration set including said at least two matching data pairs;

- creating a conversion function based on said calibration set;

- subsequently obtaining one or more additional reference data points and creating one or more new matched data pairs; and

- evaluating said calibration set when said new matched data pair is created, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pairs in said calibration set span a predetermined time range, 2) ensuring matched data pairs in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pairs over said predetermined time range, and 4) allowing matched data pairs only within a predetermined range of analyte values.

65. A computer system for maintaining calibration of a glucose sensor, the computer system comprising:

- a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;



a reference input module that receives reference data from a reference analyte monitor, including two or more reference data points;

a processor module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data and subsequently forms a calibration set including said two or more matched data pairs; and

a calibration evaluation module that evaluates said calibration set when said new matched data pair is provided, wherein evaluating said calibration set includes at least one of 1) ensuring matched data pairs in said calibration set span a predetermined time period, 2) ensuring matched data pairs in said calibration set are no older than a predetermined value, 3) ensuring said calibration set has substantially distributed high and low matched data pairs over a predetermined time range, and 4) allowing matched data pairs only within a predetermined range of analyte values,

wherein said conversion function module is programmed to re-create said conversion function of such modification is required by said calibration evaluation module.